

Morgan Lewis

Christopher J. McAuliffe

Of Counsel

+1.609.919.6619

christopher.mcauliffe@morganlewis.com

September 30, 2021

VIA ELECTRONIC MAIL

Rebecca Serfass (3ED22)

Serfass.Rebecca@epa.gov

U.S. Environmental Protection Agency, Region III

Re: Request for Information Pursuant to Section 3007(a) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6927(a) dated August 5, 2021, EPA Id No. PAD980715536, Reference Number: C21-033

Dear Ms. Serfass:

This firm represents the Hospital of the University of Pennsylvania ("HUP" or the "Hospital") and I have been asked to assist the Company in responding to the above-referenced request for information (the "Request"). The Hospital is producing these responses and documents without admission of violation or liability.

The Hospital has undertaken a diligent effort to respond to EPA's Requests, and, based on its current information and belief formed after reasonable good-faith inquiry, provides responses to EPA's inquiries below and the supporting documents enclosed with this letter. The Hospital's review and collection of records is on-going and it reserves all rights to supplement this response and provide additional documents as additional information becomes available. Due to the voluminous amount of documents potentially responsive to the Requests, we have marked each of the pages we are producing with "HUP" and a number to facilitate any discussions we have with respect to the documents. The documents are being sent to you through a secure file transfer email.

We also note several general objections to and comments on the form and content of EPA's Requests. These objections and comments apply to the Requests as a whole and individually, and are appended to this letter at Attachment 1. In some instances, we have additional or more specific comments to individual inquiries, and these are noted in the body of the individual responses. Without waiving these objections, the Hospital responds to EPA's Requests. The Hospital reserves all rights with respect to these responses and documents.

Unless otherwise noted, the Hospital's responses to these requests relate to the Hospital's generation, management and disposal of waste under EPA Id No. PAD980715536, because that is the EPA Id. number referenced at the beginning of EPA's request for information.

Morgan, Lewis & Bockius LLP

502 Carnegie Center

Princeton, NJ 08540-6241

United States

+1.609.919.6600

+1.609.919.6701

A Pennsylvania Limited Liability Partnership | Steven M. Cohen, Partner-in-Charge

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We would like to continue discussions with you. We do not have a clear understanding of your concerns, if any, but would appreciate the opportunity to address them. Please also let me know if you have any questions following your review of these responses and documents.

We have repeated below in italics each of the Requests followed by our responses. The requested certification appears at the end of the responses.

Very truly yours,

s/ Christopher McAuliffe

Christopher J. McAuliffe

CJM/djj

Responses of Hospital of the University of Pennsylvania

1. Regarding the Facility's process and waste generation, please describe in detail the Facility's waste generation processes, including a description of raw materials, all waste streams (hazardous and nonhazardous), and finished products.

a. Does the Facility track the amount of each waste stream it generates over time? If so, (1) please explain how the Facility measures that amount and (2) state how often such measurements are taken, for example daily, weekly, monthly, or for some other predetermined period of time.

b. Please state, as precisely as possible, how much of each waste stream has been generated by the Facility in each calendar month for the time period of August 1, 2017 up to the present and provide the basis of your knowledge. If you cannot state the amounts on a monthly basis, please state how much of each waste stream has been generated during the smallest intervals (e.g., daily, weekly) for which you are capable of providing such information.

c. Please provide records documenting monthly hazardous waste generation rates at the Facility.

Response: The Hospital of the University of Pennsylvania ("HUP" or the "Hospital") is an acute care hospital that generates hazardous waste from hospital operations including pharmaceutical waste from clinical operations. Crothall Healthcare manages HUP's pharmaceutical waste compliance program, including packaging, manifesting and shipping waste offsite for disposal. Stericycle Inc. ("Stericycle") ships HUP's pharmaceutical waste offsite for disposal. Stericycle in April 2019 began using EPA Id. No. PAD980715536 on manifests for pharmaceutical hazardous waste generated at HUP. Non-pharmaceutical hazardous waste from HUP is managed and manifested separately from the pharmaceutical waste. Stericycle manages the disposal of HUP's non-hazardous solid waste separately from the hazardous waste streams.

(a) Stericycle supports HUP's pharmaceutical waste program since 2019. Stericycle generates a report that can show waste streams, weight, and relevant waste codes for pharmaceutical waste on a monthly basis.

(b) Please see response to question 1(c), below.

(c) The report included with this response as document No. HUP-000959 through HUP-001022 shows volumes of pharmaceutical hazardous waste generated by HUP from April 2019 to August 2021. Starting in April 2019, Stericycle, the third-party contractor retained to manage HUP's pharmaceutical waste for disposal, began using EPA Id. No. PAD980715536 to manage and track HUP's pharmaceutical waste disposal.

2. Regarding a Facility contingency plan that describes the actions Facility personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste, including the requirements set forth at 40 C.F.R. 265.50, please provide the following information:

a. Please state "yes" or "no": Did the Facility have a documented contingency plan in effect at the time of July 2019?

- i. *If “yes”, please submit a copy of the contingency plan that was in effect at July 2019 and state the date that it was completed and in effect.*
- ii. *If “no”, please submit a copy of the contingency plan currently in effect at the Facility and indicate the date it was completed and in effect.*

Response: The Hospital is subject to the Emergency Response Plan for the Main Campus (the “ERP”) adopted by the University of Pennsylvania. The ERP is revised as of January 11, 2021, and an earlier version was in effect at July 2019. A copy of the ERP is included with the records being submitted to EPA with this response. See HUP-001023 through HUP-001060.

3. *Regarding the submission of Biennial Reports required under 40 C.F.R. 262.41, please provide the following information:*

- a. *Indicate by stating “yes” or “no”: (1) Did the Facility submit a Biennial Hazardous Waste Report for the 2017 and 2019 calendar years?*
- b. *If you answered “yes”, please provide a copy of such submissions as an attachment to your response.*
- c. *If you answered “No”, please explain, in detail, why the Facility did not timely submit a Biennial Hazardous Waste Report for the 2017 and 2019 calendar years.*

Response: (a) The Hospital did not dispose of waste under EPA ID No. PAD980715536 during the time period that would have been subject to a Biennial Hazardous Waste Report for calendar year 2017. The Hospital did not make a timely submission of a 2019 Biennial Hazardous Waste Report for pharmaceutical hazardous waste under EPA Id. No. PAD980715536, but as a corrective action is submitting the report to EPA.

(b) A copy of the 2019 Biennial Hazardous Waste Report with respect to EPA ID No. PAD980715536 for HUP’s pharmaceutical hazardous waste dated September 10, 2021 is included with the records being submitted to EPA with this response. See HUP-000001 through HUP-000012.

(c) The Hospital did not dispose of waste under EPA ID No. PAD980715536 during the time period that would have been subject to a Biennial Hazardous Waste Report for calendar year 2017. HUP did not timely submit a 2019 Biennial Hazardous Waste Report for its pharmaceutical waste because it did not realize until after the deadline for submission that Stericycle Inc. had used EPA Id. No. PAD980715536 for pharmaceutical waste subject to HUP’s newly implemented pharmaceutical waste program.

4. *Regarding conducting and documenting inspections of hazardous waste accumulation areas (“HWAA”) located at the Facility, as required by 40 C.F.R. 265.174, please provide the following information:*

- a. *Describe each HWAA used to accumulate hazardous waste at the Facility. Include a description of how the waste is stored (i.e. metal 55-gallon drums, polypropylene 250-gallon totes, etc.) and a site plan depicting the location(s) of each HWAA.*

- b. *With respect to each of the HWAAs located at the Facility, does the Facility inspect containers being stored in the HWAAs for leaking containers and deterioration of the containers caused by corrosion or other factors?*
- c. *If you answered "yes" to Question 4.b., above, please state how often the inspections are conducted.*
- d. *If you answered "yes" to Question 4.b., above, provide the first and last name of each person at the Facility who is or was responsible for conducting the inspections of the Facility's HWAAs for the time period of August 1, 2017 up to the present.*
- e. *Submit a copy of any and all inspection logs maintained by the Facility for the HWAAs for the time period of August 1, 2017 up to the present.*

Response: (a) HUP's pharmaceutical hazardous waste accumulation area is the central accumulation area ("CAA") on the Rhoads dock. There is a pharmaceutical hazardous waste CAA for the Perelman Center for Advanced Medicine, which is part of the HUP campus in an adjacent building, adjacent to the loading dock at the Perelman Center. We are working with our contractors to ensure that manifests properly identify the location where pharmaceutical hazardous waste is collected. Pharmaceutical waste is stored in rigid, plastic DOT shippable containers. A site plan depicting the locations of the CAAs are included with the documents provided with this response. See HUP-001061.

(b) HUP inspects the containers in the CAAs for leaking and deterioration.

(c) Inspections are conducted weekly.

(d) Jeff Henne, who is the Hospital Safety Manager since August 1, 2017, is responsible for conducting the inspections.

(e) Inspection logs for the Rhoads dock from the start of disposal under EPA Id No. PAD980715536 are included with the documents provided with this response. See HUP-000013 through HUP-000043.

5. Regarding the Facility's hazardous waste training program for which requirements are described in 40 C.F.R. § 265.16, please provide the following information:

- a. *Provide the first and last name of each employee at the Facility who is or has been responsible for the handling and/or management of hazardous waste for the time period of August 1, 2017 up to the present. This would include, but not be limited to, persons responsible for the labeling, dating, inspecting, and transporting containers of hazardous waste, in addition to the signing of manifests and Land Disposal Restriction notices, waste determinations, emergency coordinators, and hazardous waste training instructors.*
- b. *Provide the exact dates of employment for each of the employee names provided in your response to Question 5.a. above.*
- c. *Please state "yes" or "no" to the following question: Does the Facility maintain documentation specifying the job title and job description for each employee listed in response to Question 5.a. above? If "yes", please answer the following:*
 - i. *Submit the Facility's documented job titles and written job descriptions for each employee listed in response to Question 5.a.*

- ii. *For each document submitted in response to Question 5.c.i, above, provide the date each document was first created by the Facility.*
- d. *Please state "yes" or "no" to the following question: Has the Facility provided initial hazardous waste training to each employee listed in response to Question 5.a.? If "yes", please answer the following:*
 - i. *Provide the dates on which initial hazardous waste training was conducted for each of the employees listed in response to Question 5.a. and state the basis of your knowledge.*
 - ii. *Submit any and all records the Facility has maintained to document initial hazardous waste training has been conducted for each employee named in response to Question 5.a. for the time period of August 1, 2017 up to the present.*
- e. *Please state "yes" or "no" to the following question: Has the Facility provided annual refresher hazardous waste training to each employee listed in response to Question 5.a.? If "yes", please answer the following:*
 - i. *Provide the dates on which annual refresher hazardous waste training was conducted for each of the employees listed in response to Question 5.a. for the time period of August 1, 2017 up to the present and state the basis of your knowledge.*
 - ii. *Submit any and all records the Facility has maintained to document annual fresher hazardous waste training has been conducted for each employee named in response to Question 5.a. for the time period of August 1, 2017 up to the present.*

Response: (a) Crothall Healthcare and Stericycle provide employees responsible for the management and disposal of HUP's pharmaceutical waste that was manifested under EPA Id. No. PAD980715536. In addition, Jeff Henne and Kevin Heym have responsibility for overseeing the handling and/or management of hazardous waste. Training records for the personnel that manage waste within the hospital and may sign manifests for that waste associated with EPA Id. No. PAD980715536 are included with the records produced with this response. Additionally, training records for Jeff Henne and Kevin Heym are included with the records produced with this response.

(b) Please see training records documentation included with the records provided with this response. Jeff Henne has been HUP's Hospital Safety Manager since August 1, 2017. Kevin Heym was hired on June 18, 2007 and is HUP's Manager of Environmental Hygiene Services.

(c) Yes, see job descriptions for the Crothall Healthcare employee and the job descriptions for HUP's Safety personnel included with the records produced with this response.

(d)(i)&(ii) Crothall Healthcare and Stericycle provide training for their employees and the HUP employees identified in the response to 5(a). Please see the training records included with the records provided with this response.

(e)(i)&(ii) Crothall Healthcare and Stericycle provide training for their employees and the HUP employees identified in the response to 5(a). Please see the training records included with the records provided with this response.

See HUP-000105 through HUP-000264 and HUP-000287 through HUP-000288 for training records including hire dates.

See HUP-000265 through HUP-000286, and HUP-000289 through HUP-000301 for job descriptions of positions filled by Crothall Healthcare employees at HUP and the HUP employees identified in 5(a) above.

6. *Submit copies of any and all hazardous waste manifests generated by the Facility for the off-site shipments of hazardous waste that occurred from August 1, 2016 to present.*

Response: Manifests associated with EPA Id. No. PAD980715536 for the period April 2019 to August 2021 are included with the records provided with this response. See HUP-000302 through HUP-000958.

7. *Based on a review of e-Manifest data, it appears shipments of hazardous waste began under the PAD980715536 RCRA ID number in July 2019. Please state whether the Facility was generating hazardous waste prior to this date.*

a. *If you answered “yes” to question 7 above, describe under what facility name and RCRA ID number under which the hazardous waste was managed and shipped off-site. Provide hazardous waste manifests or other off-site shipping documents for the hazardous waste that was generated at UPenn Hospital and shipped off-site from August 1, 2016 to present that is not otherwise included in your response to question 6 above.*

b. *If you answered “no” to question 7 above, describe in detail what changed in the Facility’s waste generation processes or handling methods in July 2019.*

Response: HUP generated hazardous waste prior to July 2019.

(a) Prior to the implementation of the pharmaceutical hazardous waste program, hazardous waste from HUP was managed and shipped offsite with other hazardous waste from the University of Pennsylvania. The University consolidates hazardous waste from its different operations, which precludes the identification of manifests that relate solely to waste from HUP.

(b) Not applicable.

8. *Regarding copies of Land Disposal Restriction Notification (“LDR”) forms for the off-site shipments of hazardous waste:*

a. *Please state “yes” or “no”: has the Facility provided LDR forms for each hazardous waste stream shipped offsite to each treatment, storage, and disposal facility (“TSDF”) it has shipped to? If yes, provide a copy of all LDR forms.*

b. *If the Facility generated or retrieved copies of any of the LDR forms from the TSDF (or other off-site provided) subsequent to the receipt of this letter, please also indicate which LDR forms for which this the case and the date(s) when such forms were generated or obtained.*

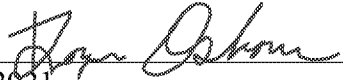
Response: (a) LDR forms are included with the records provided with this response for the waste disposed of under EPA Id. No. PAD980715536.

(b) HUP obtained the LDR forms included with the records provided with this response from Stericycle, who manages the disposal of HUP’s pharmaceutical waste.

See HUP-000302 through HUP-000958 for waste disposal records.

Certification

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate and complete.

Signature: 

Date: 09/30/2021

Name: Roger Osbourn

Title: Corporate Director of Emergency Management & Safety

ATTACHMENT 1
General Objections and Comments Applicable to Each Request

1. The Hospital objects to the Requests to the extent they seek information or documents that are subject to applicable privileges, including the attorney-client privilege, the attorney work product protection, the self-evaluation privilege, or which are otherwise not discoverable. Such information or documents will not be produced. The Hospital also objects to the Requests to the extent they require the production of trade secrets and commercial and financial information, as well as other confidential documents and information.

2. The Hospital objects to the Requests on grounds that they are unduly burdensome and overly broad, seeks information not relevant to EPA's RCRA enforcement and compliance interests, is vague, ambiguous, and unclear concerning its scope or otherwise, includes inquiries that are subject to a variety of interpretations, requires that legal conclusions be made, calls for the creation of documents not kept in the normal course of business or as required by RCRA or implementing regulations, and is otherwise unreasonable, thereby exceeding EPA's authority under RCRA.

3. The Hospital objects to the Requests seeking a certification that is outside EPA's authority under 42 U.S.C. §6927.

4. The Hospital objects to the Requests referring to the Hospital as a "Facility." The Hospital's responses to the Requests should not be interpreted as an admission that the Hospital is a "Facility."

5. The Hospital's responses to the Requests are based on its current information and belief formed after a diligent and reasonable, good faith inquiry. Where EPA's inquiries are vague, ambiguous or overly broad, The Hospital has made appropriate and reasonable efforts to interpret these inquiries to the best of its ability. Subject to and without waiving these objections, information is provided based on The Hospital's interpretation of specific terms and items in the Requests. We have not, however, included every document that may be construed to fall within the scope of the Requests.

6. The Hospital objects to the Requests to the extent they purport to require a search for pre-existing documents available only in electronic format, such as pre-existing e-mails or electronic files, including without limitation, backup of e-mail or computer networks. Such a search would be unduly burdensome and not possible within the timeframe allowed for a response. Further, The Hospital has interpreted EPA's Requests to apply to final versions of documents only and has not included drafts or work papers.

7. The Hospital's production of documents does not represent or act as an admission by the Hospital that the contents of the documents are true, correct or accurate; nor does it act to authenticate such documents for the purposes of admissibility in any administrative or judicial proceeding.

8. The Hospital objects to the Requests to the extent they seek the production of documents and information already in the possession of EPA or information that is equally available to the government and the Hospital.

9. The Hospital's submission of its responses and documents is made without waiver of any objections, privileges, or rights, and is not an admission of liability under federal or state law.